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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,214	04/14/2004	John F. Burd	OCULIR04	6280

27189 7590 08/24/2004

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EXAMINER
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KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/824,214

**Applicant(s)**

BURD ET AL.

**Examiner**

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/14/2004</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 7-9, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Application Publication 2002/0049389 to Abreu. Abreu teaches exposing the conjunctiva to infrared energy, detecting the reflectance spectrum, and determining the concentration of interest based on the spectrum. (paragraph 0424 of Abreu). In regard to claim 2, the subject is human. (paragraph 0203 of Abreu). In regard to claims 3-4, the analyte is glucose. (paragraph 0429 of Abreu). In regard to claim 5, mid-infrared radiation is used. (paragraph 0276 of Abreu). In regard to claim 8, a filtering apparatus 2304 is used. (Fig. 85 of Abreu). In regard to claim 9, a processor 2324 is used. (Fig. 85 of Abreu). In regard to claim 12, Abreu discloses a computer processor with a computer program (a data processing unit), a memory (recording unit), and a communications interface (a modem). (paragraph 0151 of Abreu). It is noted that the limitation “for downloading and storing data collected according to claim 1” in claim 12, line 1 is merely “intended use” language, which cannot be relied upon to define over Abreu, since Abreu discloses all of the claimed elements and their recited relationships. See *Ex parte Masham* 2 USPQ 2<sup>nd</sup> 1647. In regard to claim 13, Abreu teaches

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downloading measurements to a computer system (a hospital based computer system).  
(paragraph 0151 of Abreu).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0049389 to Abreu as applied to claim 5, and further in view of U.S. Patent 6,039,697 to Wilke et al. (Wilke). Abreu teaches that mid-infrared radiation is used (paragraph 0276 of Abreu) but does not teach specific wavelengths. Wilke teaches suitable wavelengths that are between 4-8 microns (column 4, lines 25-34 of Wilke), which would fulfill the requirements of providing mid-infrared wavelengths as set forth in Abreu. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the wavelengths as disclosed by Wilke since Abreu teaches that mid-infrared wavelengths can be used and Wilke teaches such wavelengths.

***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

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unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claim 12 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 35 of copending Application No. 10/428410 ('410). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 35 of '410 and claim 12 of the present invention claim a computer system comprising the elements of (a) a computer processor, (b) a memory, (c) a communications interface, and (d) a computer program. The only distinction between these claims is the limitations "for downloading and storing data, collected from an instrument according to claim 12 or 23" in claim 35 of '410 and "for downloading and storing data, collected according to claim 1" in claim 12 of the present application, which is merely "intended use" language that does not add any structural limitation to the claimed inventions. Also, it is noted that the "data" in both claims are referring to the same type of data, particularly infrared spectra and analyte concentrations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claim 12 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-21 of copending Application No. 10/824254 ('254). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 20 of '254, claim 21 of '254, and claim 12 of the present invention claim a computer system comprising the elements of (a) a computer processor, (b) a memory, (c) a communications interface, and (d) a computer program. The only distinction between these claims is the limitations "for downloading and storing data, collected according to the method of claim 1" in claim 20 of '254, "for downloading and storing data, collected according to the method of claim 12" in claim 21 of '254, and "for downloading and storing data, collected according to claim 1" in claim 12 of the present application, which is merely "intended use" language that does not add any structural limitation to the claimed inventions. Also, it is noted that the "data" in all three claims are referring to the same type of data, particularly infrared spectra and analyte concentrations.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-11 of copending Application No. 10/428410 ('410) in view of U.S. Patent Application Publication 2002/0049389 to Abreu. Claim 1 of '410 claims exposing a body surface to

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mid-infrared radiation (which is narrower in scope than electromagnetic radiation), detecting mid-infrared radiation (which is narrower in scope than electromagnetic radiation), and determining a radiation signature to determine an analyte concentration.

Claim 1 of the present application does not claim a particular body surface. Abreu teaches that a human conjunctiva is a suitable body surface (paragraph 0424 of Abreu) that would fulfill the requirements of providing a body surface as set forth by claim 1 of the present invention. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the method of claim 1 on the human conjunctiva as disclosed by Abreu since claim 1 requires a body surface and Abreu teaches one suitable surface. In regard to claim 2 of the present application, claim 2 of '410 claims "wherein said method is non-invasive and wherein said subject is a human". In regard to claim 3 of the present application, claim 3 of '410 claims "wherein said analyte is selected from the group consisting of metabolic compounds or substances, carbohydrates, sugars, glucose, proteins, peptides, amino acids, fats, fatty acids, triglycerides, polysaccharides, alcohols, ethanol, toxins, hormones, vitamins, bacteria-related substances, fungus-related substances, virus-related substances, parasite-related substances, pharmaceutical compounds, non-pharmaceutical compounds, pro-drugs, drugs, and any precursor, metabolite, degradation product or surrogate marker". In regard to claim 4 of the present application, claim 4 of '410 claims "wherein said analyte is glucose". In regard to claim 5, claim 1 of '410 claims mid-infrared radiation. In regard to claim 6, claim 6 of '410 claims "wherein the mid-infrared radiation...is in a wavelength range of about 2.5 microns to about 25.0 microns". In

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regard to claim 7 of the present application, claim 7 of '410 claims "wherein said detecting step further comprises selecting and detecting said mid-infrared radiation". In regard to claim 8 of the present application, claim 8 of '410 claims "wherein said selecting of said reflected mid-infrared radiation further comprises filtering said reflected mid-infrared radiation". In regard to claim 9, claim 9 of '410 claims "wherein said detecting step and said determining steps further comprise using a microprocessor". In regard to claim 10 of the present application, claim 10 claims "wherein said reflected mid-infrared radiation comprises infrared radiation having wavelengths between about 2.5 microns to about 25.0 microns". In regard to claim 11 of the present application, claim 11 of '410 claims "wherein said reflected mid-infrared radiation is within the wavelengths between about 2.5 microns to about 11.0 microns".

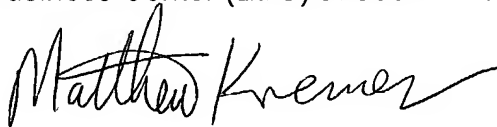
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 3736



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